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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,323	02/27/2004	Christian Stapper	DEAV2003/0016 US NP	9610
5487	7590	06/02/2006	EXAMINER	
ROSS J. OEHLER SANOFI-AVENTSI U.S. LLC 1041 ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807			VALENROD, YEVGENY	
			ART UNIT	PAPER NUMBER
			1621	
DATE MAILED: 06/02/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/789,323

Applicant(s)

STAPPER ET AL.

Examiner

Yevgeny Valenrod

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

**DETAILED ACTION**

***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, 3, 4, 5 (in part) and 6-10 are drawn to Compound of formula I, where Ring A is (C3-C8)-cycloalkanediyl or (C3-C8)-cycloalkenediyl and R is NR<sub>1</sub>R<sub>2</sub> or OR<sub>1</sub>, classified in class 560, subclass 8+.
- II. Claims 1, 2, 3, 4, 5 (in part) and 6-10 are drawn to Compound of formula I, where Ring A is (C3-C8)-cycloalkanediyl or (C3-C8)-cycloalkenediyl and R is (C6-C10)-aryl, classified in class 560, subclass 8+.
- III. Claims 1, 5 (in part) and 6-10 are drawn to Compound of formula I, where Ring A is (C3-C8)-cycloalkanediyl or (C3-C8)-cycloalkenediyl and R is (C5-C12)-heteroaryl classified in class 560, subclass 8+.
- IV. Claims 1, 5 (in part) and 6-10 are drawn to (C3-C8)-cycloalkanediyl or (C3-C8)-cycloalkenediyl where at least one carbon atom is replaced by an oxygen atom and R is NR<sub>1</sub>R<sub>2</sub> or OR<sub>1</sub>, classified in class 560, subclass 8+.
- V. Claims 1, 5 (in part) and 6-10 are drawn to (C3-C8)-cycloalkanediyl or (C3-C8)-cycloalkenediyl where at least one carbon atom is replaced by an oxygen atom and R is (C6-C10)-aryl, classified in class 560, subclass 8+.
- VI. Claims 1, 5 (in part) and 6-10 are drawn to (C3-C8)-cycloalkanediyl or (C3-C8)-cycloalkenediyl where at least one carbon atom is replaced by an

oxygen atom and R is (C5-C12)-heteroaryl classified in class 560, subclass 8+.

- VII. Claims 11-17, drawn to methods of use of compound of formula I where the compound is as defined by group I, classified in class 514, subclass 506+.
- VIII. Claims 11-17, drawn to methods of use of compound of formula I where the compound is as defined by group II, classified in class 514, subclass 506+.
- IX. Claims 11-17, drawn to methods of use of compound of formula I where the compound is as defined by group III, classified in class 514, subclass 506+.
- X. Claims 11-17, drawn to methods of use of compound of formula I where the compound is as defined by group IV, classified in class 514, subclass 506+.
- XI. Claims 11-17, drawn to methods of use of compound of formula I where the compound is as defined by group V, classified in class 514, subclass 506+.
- XII. Claims 11-17, drawn to methods of use of compound of formula I where the compound is as defined by group VI, classified in class 514, subclass 506+.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VI and VII-XII are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the products as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the methods of using products of groups I-IV can be practiced with materially different product. For example, Glucophage (metformin hydrochloride), which is structurally different from any of the compounds claimed by the applicant, can be used to treat insulin resistance.

Inventions I-VI directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the products vary either in the identity of Ring A and/or identity of the R group. Heterocyclic compounds have chemical and physical characteristics that are different from cycloalkyl compounds. Heterocyclic compounds are more polar than the corresponding cycloalkanes, can be acidic or basic and have different reactivity. For example a compound containing cyclopentane does not render obvious a compound where the cyclopentane is replaced with tetrahydrofuran.

Identity of the R-group significantly changes the properties of the compound of formula I. When R is aryl, the polarity, reactivity and the potential physiological effect of

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that group is different from when R is heteroaryl or when R is NR<sup>1</sup>R<sup>2</sup>. It is not obvious to replace an aryl group with an amino containing acyclic group nor is it obvious to replace aryl group with a substituted heteroaryl. Inventions I-VI represent distinct compounds of formula I and are therefore restricted.

Inventions VII-XII are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the compounds to be used for the claimed treatments are different in structure and are not obvious variants of each other for the reasons described in the previous paragraph. The methods of using these compounds are therefore distinct methods.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

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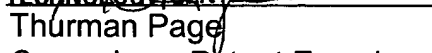
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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